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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/585,742	Applicant(s) HIRAMATSU ET AL.	
	Examiner MARCIA S. NOBLE	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/2006, 1/31/2007, & 9/8/2008</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-26 are pending. Claims 3, 4 6, 9-19, 22, 23, 25, and 26 are amended by the preliminary amendment filed 7/12/06. Claims 1-26 are under consideration.

Information Disclosure Statement

The information disclosure statement filed 11/22/2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

In the case, a list of all patents, publications, applications, or other information to be considered was not submitted. Therefore, the information disclosure statement could not be considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1632

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 18, 19, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al (US 2002/0137211 A1 pub date:9/26/2002; of record).

Liu et al disclose a transgenic silkworm comprising a nucleic acid encoding a spider dragline protein 1 operably linked to a fibron L chain promoter (p. 1, [0005], line 1 to [0009], line 3). This disclosure encompasses the limitations of claim 19 because silkworms have an endogenous pair of fibroin chain genes and the transgene is present in a region other than the pair of fibroin chain genes. Liu et al disclose that transgene expression results in a produces a silk thread comprising complete L chain-dragline fusion protein (p. 1, [0012], lines 1-15). This disclosure encompasses the limitations of the silk tread of claims 1-3, 18, and 25. Claims 6-8 recites wherein the spider thread content is various ranges within 0.1-25 wt%. Because the wt% does not structurally alter the claimed silk tread, the disclosure by Liu et al also encompass the limitations of claims 6-8. Liu et al discloses a method of producing a transgenic silkworm expressing a spider dragline protein in its fibron L chain that utilizes a piggyBac transposon (p. 1, [0004], line 1 to [0009], last line). This disclosure encompasses the limitations of claims 23 and 24.

Thus, Liu et al anticipated the instantly claimed invention because Liu et al discloses all the limitations of the claims.

Claims 1, 9-11, 15, 18, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahnstock et al (WO 94/29450 pub date:12/22/1994; of record).

The breadth of the claims encompasses a spider thread protein solely. The claims recite that the claimed thread is characterized by being produced by a transgenic silkworm possessing a pair of fibroin H chain genes. However, this is not a structural limitation of the product but rather the transgenic silkworm. The thread itself does not require any other structural elements other than the spider thread protein. Therefore, the instant claims encompass thread comprising a spider dragline protein.

Fahnstock et al discloses the amino acid sequence of a spider dragline protein variant of spidroin 1, DP-1B.16 monomer, which is encompassed by SEQ ID NO:63 (p. 106, and p. 9, lines 32-24). This amino acid sequence comprising 100% sequence identity with SEQ ID NO:1 of instant claim 9, and therefore discloses the limitations of this claims 1, 9, and 18. Claims 10 and 11 specify a thread with 3-30 repeats or 4-16 repeats of the claims peptide. The breadth of the samples encompass any peptide from SEQ ID NO:1 with at least 3 or 4 repeating peptides. A peptide encompasses any amino acid sequence encompassing at least two amino acids. SEQ ID NO:63, as disclosed by Fahnstock et al, comprises 9 repeat AA sequences and at least 3 repeat AAA sequences. The sequence also comprises at least 30 copies of the repeating GXG motif present in the spidroin 1(p. 5, lines 16-33). Therefore, SEQ ID NO:63 also encompasses the limitations of claims 10 and 11. Fahnstock et al discloses the spider thread variants, which include SEQ ID NO:63, are applicable use in clothing (p.

Art Unit: 1632

16, lines 8-10). Therefore, Fehnestock et al discloses the limitations of a textile employing the silk thread, as claimed in claim 26.

Claim 15 encompasses a silk thread comprising a peptide sequence of SEQ ID NO:1 and a peptide sequence of SEQ ID NO:2. The claims do specify that the peptide sequence from SEQ ID NO:1 and must be a different sequence than the peptide sequence from SEQ ID NO: 2. Therefore, if SEQ ID NOS: 1 and 2 have the a peptide sequence in common. This common sequence will anticipate the claim.

SEQ ID NO:63 as taught by Fehnestock comprises multiple GAG sequences throughout the sequence. Also does SEQ ID NO:2. Therefore, the disclosure of the GAG sequence in SEQ ID NO: 63 that are also common to both SEQ ID NO:1 and SEQ ID NO:2, encompasses the limitations of the claims.

Therefore, Fehnestock et al anticipates the instant claims because it discloses all the limitations of the claims.

Claims 1, 12-14, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cappello et al (US 20020045567 A1 pub date:4/18/2002).

The breadth of the claims encompasses a peptide with similarities to spider thread protein encompassed by SEQ ID NO:2. The claims recite that the claimed thread is characterized by being produced by a transgenic silkworm possessing a pair of fibroin H chain genes. However, this is not a structural limitation of the product but rather the transgenic silkworm. The thread itself does not require any other structural elements other than peptides of spider thread protein. The claims more broadly

Art Unit: 1632

encompass any portion or alteration to the sequence of SEQ ID NO:2. Therefore, any sequence that has some structural identity to SEQ ID NO:2 will encompass the limitations of the claims.

Cappello et al disclose SEQ ID NO:9 which has 69.3% identity with SEQ ID NO:2. SEQ ID NO:9 has 8 repeats of GSGAGA between amino acids 99-147 that are identical to amino acids 47-95 of SEQ ID NO:2. Therefore, SEQ ID NO:9 meets the limitations of claims 1, 12-14, and 18.

Claim 15 encompasses a silk thread comprising a peptide sequence of SEQ ID NO:1 and a peptide sequence of SEQ ID NO:2. The claims do specify that the peptide sequence from SEQ ID NO:1 and must be a different sequence than the peptide sequence from SEQ ID NO: 2. Therefore, if SEQ ID NOS: 1 and 2 have the a peptide sequence in common. This common sequence will anticipate the claim.

SEQ ID NO:9 comprises multiple GAG sequences throughout the sequence. Also does SEQ ID NO:1. Therefore, the disclosure of the GAG sequence in SEQ ID NO: 9 that are also common to both SEQ ID NO:1 and SEQ ID NO:2, encompasses the limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toray (CA 2,478,205 pub date: 12/09/2003; of record), in further view of Fehnestock et al (WO 94/29450 pub date:12/22/1994; of record).

Toray teaches the production of a transgenic silkworm comprising transgene encoding an exogenous protein operably linked to the fibrion H chain promoter using a piggyBac transposon (p. 8, lines 30-35; p. 20, line 31 to p. 21, line 1). Toray teaches that the transgene construct can comprise the first exon, first intron, and at least a sufficient amount of the second exon of the H chain gene, which encodes for the H chain promoter (p. 17, lines 1-25). Toray teaches that the transgene construct comprises the full length of the coding sequence of the H chain protein and that the gene sequence that encodes for the exogenous protein can be inserted in the region of the H chain gene encoding for region around the 20th residue of the C terminal of the H chain. When expressed in a transgenic silkworm, the resultant product is a fibrion fiber comprising an H chain comprising an exogenous protein incorporated into the C

Art Unit: 1632

terminal of the H chain, whose sequence corresponds to SEQ ID NO:3 of the instant application, that is disulfide bonded to with the fibrion L chain via the cysteine residue in the C terminal of the H chain(p. 18, lines 3-30). Toray also teaches the nucleic acid encoding the exogenous protein can be inserted 3' of the promoter (p. 17, lines 6-9). This construct formation would result a thread comprising a H chain with an exogenous protein inserted in the N terminal region of the H chain, whose sequence corresponds to SEQ ID NO:4. Further, the above disclosures teach the method of producing a silk thread produce comprising an exogenous protein. Toray also teaches that the use of their silkworm system overcomes many of the transcriptional and translational problems of E coli systems and provides for large scale production of exogenous protein that is more easily harvested than previous transgenic silkworm technologies (p. 1, lines 34 to p. 2, line 4; p. 4, line 32 to p. 5, line 12; p. 6, lines 33-35). Therefore, Toray provides a motivation to use their transgenic silkworm technology for mass production of an exogenous protein of interest. Toray does not teach that the exogenous protein is a spider thread protein, or more specifically a spider thread protein of SEQ ID NO:1 and/or 2 or a portion thereof SEQ ID NOS:1 and/or 2.

However, Fehnestock et al et al teaches multiple nucleic acid sequences and expression constructs that encode for spider dragline protein variants, including variants encoding spidroin 1 and 2 (p. 9, lines 7-24; p. 10 , line 1 to p. 11, line 4). Fehnestock et al teaches an interest in mass production of spider dragline proteins and variants thereof because they have a tensile strength of over 200ksi with an elasticity of nearly 35%, which make it more difficult to break than either KEVLAR or steel. Fehnestock et

Art Unit: 1632

al further teaches that when spun into fibers, these threads may have application in bulk clothing, high strength rope, and surgical sutures (p. 16, lines 3-14). Therefore, Fehnestock et al provides motivation to mass produce the dragline proteins by recombinant technologies.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Art Unit: 1632

In the present situation, rationales A, B, and G are applicable. At the time of the invention, it would have been obvious to an artisan of ordinary skill that they could substitute any of the nucleic acid sequences encoding a spider dragline protein, as taught by Fehnestock et al into the methods of the making a transgenic silk worm, taught by Toray et al to predictably produce a transgenic silkworm expressing a spider dragline protein and producing a silk tread comprising a spider drag line protein with a reasonable expectation of success. An artisan of ordinary skill would be motivated to combine the teaching of the prior art of Toray and Fehnestock because Fehnestock teaches a motivation to mass produce spider dragline protein and Toray teach a superior recombinant technology for large scale productions of such proteins of interest with greater ease of harvesting such proteins.

Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both Graham and KSR.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A transgenic silkworm comprising in its genome a nucleic acid encoding a spider thread protein operably linked to a promoter that results in express of said spider thread protein in a silkworm silk thread, does not reasonably provide enablement for 1) a transgenic silkworm comprising a transgene that is not incorporated into the genome; and 2) does not comprise all the elements of the construct that are essential for expression of the transgene product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

1) The transgenic silkworm claims of 19-22 encompass a transgenic silkworm that comprises an ectopic transgene that is therefore not incorporated into the genome of said silkworm. The specification fails to provide specification guidance to teach a silkworm that does not incorporate the transgene into it genome. Therefore, the

Art Unit: 1632

specification does not enable embodiments of the instant invention that encompass a transgenic silkworm that comprises a transgene that is not incorporated into the genome.

Further, at the time of the invention, the art teaches that transgenic animals comprising a transgene that has not integrated into the genome can be produced, however, expression and stable retention of this transgene is highly unpredictable. For example, Naito et al (J Reprod Fert 113:137-143, 1998) teaches the production of transgenic bird embryos comprising a LacZ transgene that did not incorporate into the genome but existed episomally. Naito et al reports that LacZ expression was present chick embryos 3 days after introduction of the transgene, but was dramatically reduced by 17 days post introduction of the transgene. Naito et al further reports that the gene was only detected in two live chick at hatching and that these chick had lost the transgene by maturity. Therefore, Naito et al teaches a progressive loss of transgene expression and ultimate loss of a transgene due it episomal existence (abstract).

Therefore, the instant claims are not enabled for a transgenic silkworm that does not incorporate the transgene into the genome because the specification fails to provide specification guidance to make and use such a transgenic silkworm and the art teaches that transgenic animal that do not incorporate the transgene into its genome do not predictably comprise and express their transgene.

2) Overall the instant claims do not disclose the essential elements necessary, such as a promoter operably linked to a coding sequence of a spider thread protein, for expression of a transgene or only partially disclose elements of the transgene construct.

Art Unit: 1632

Therefore, the breadth of the claims encompasses transgenic silkworm that does not have a coding sequence for a spider thread protein operably linked to a promoter.

However, the specification fails to teach such a transgenic silkworm that does not have nucleic acid encoding a spider thread protein operably linked to a promoter.

Further, for a gene to be expressed by a transgenic animal, it must minimally comprise a coding sequence for a protein of interest and the elements to direct the transcription and translation machinery of cells. This requires the presence of a coding sequence to a protein of interest and a promoter capable of driving expression in cells (Chen et al US 5,824,837 10/20/1998; see col 2, line 49-53). Therefore, the embodiments that encompass a transgenic silkworm lacking a nucleic acid encoding a spider thread protein operably linked to a promoter that directs expression of said nucleic acid to silkworm silk threads would not result in a transgenic silkworm that expresses a silkworm silk thread comprising a spider thread protein because it does not have necessary elements to do so. Further, the specification fails to provide an enabled use for a transgenic silkworm that is incapable of expressing a silk thread lacking the spider thread protein.

Therefore, the specification and art fails to teach a functional transgenic silkworm lacking a nucleic acid encoding a spider thread protein or an enabled used thereof.

Therefore, overall, at the time of filing the skilled artisan would need to perform an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 recite "the spider thread protein is ...wt%". This recitation is indefinite because it is not apparent what a wt% encompasses or what the spider thread protein is a "wt%" of. Amending the claims to more clearly identify the meaning of "wt%" and what the spider thread protein is a "wt%" of will be remedial.

Claim 23 recites a method "which utilizes a transposon". Claim 25 recites a method "characterized by using a transgenic silkworm". These recitations are indefinite because it is not apparent how the transposon is to be utilized or how the method is using the silkworm. Claim 24 depends from claim 23.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 23-25 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

Art Unit: 1632

Claims 23-25 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

Marcia S. Noble
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